RESEARCH

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Discovery

Formulation and evaluation of Sumatriptan succinate floating bilayered tablets

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General Note
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ABSTRACT

Objective of the study is to formulate and evaluate Sumatriptan succinate floating bilayered tablets using different viscosity grades of HPMC polymer i.e. HPMC K15M and HPMC K100M in combination with carboxy methyl cellulose sodium and poly ethylene oxide in different ratios in sustained release portion and superdisentegrants in immediate release portion to get a bimodal release formulation and the prepared bi-layer tablets are evaluated for some of the properties like Thickness, Hardness , Friability , Uniformity of weight, Content uniformity, *In vitro* dissolution, *In vitro* buoyancy studies for sustained layer. The optimized sustained release portion and immediate release portion (FSR4 & FIR3, FSR8 & FIR3) were compressed together to get bilayered tablet. Optimized floating bilayered tablets (BL43 and BL83) released 84.33% & 87.15 % drug in 24 hrs respectively in 0.1 N HCl. The release of the sustained layer follows first order, non-fickian diffusion. The optimized bilayered tablets were studied for *in-vitro* drug release and accelerated stability studies. The optimized tablets formulations were found to be stable during the short term accelerated stability studies (3 months). FT-IR studies indicated that there were no drug-excipient interactions.

Keywords: Sumatriptan Succinate, Floating bilayered Tablets, HPMC, Sustained Release Portion and Immediate Release Portion, Superdisintigrants.

1. INTRODUCTION

1.1. Oral Controlled Release Drug Delivery Systems

Oral controlled release drug delivery is a drug delivery system that provides the continuous oral delivery of drugs at predictable and reproducible kinetics for a predetermined period throughout the course of GI transit and also the system that target the delivery of a drug to a specific region within the GI tract for either local or systemic action (Vyas S.P, Khar R.K *et al.,* 2002). The main areas of potential challenge in the development of oral controlled drug delivery systems are (P.G.Yeole *et al.,* 2005).

1. Development of a drug delivery system: To develop a viable oral controlled release drug delivery system capable of delivering a drug at a therapeutically effective rate to a desirable site for duration required for optimal treatment.
2. Modulation of gastrointestinal transit time: To modulate the GI transit time so that the drug delivery system developed can be transported to a target site or to the vicinity of an absorption site and reside there for a prolonged period of time to maximize the delivery of a drug dose.
3. Minimization of hepatic first pass elimination: If the drug to be delivered is subjected to extensive hepatic first-pass elimination, preventive measures should be devised to either bypass or minimize the extent of hepatic metabolic effect.
4. Conventional oral controlled dosage forms suffer from mainly two adversities. The short gastric retention time (GRT) and unpredictable gastric emptying time (GET). A relatively brief GI transit time of most drug products impedes the formulation of single daily dosage forms. Altering the gastric emptying can overwhelm these problems. Therefore it is desirable, to formulate a controlled release dosage form that gives an extended GI residence time.

Extended release dosage form with prolonged residence time in stomach are highly desirable for drugs.

1. That are locally active in stomach,
2. That have an absorption window in the stomach or in the upper small intestine,
3. That are unstable in the intestinal or colonic environment,
4. Have low solubility at high pH values.

Gastro retentive Dosage Form (GRDF)

It is evident from the recent scientific and patient literature that an increased interest in novel dosage forms that are retained in stomach for a prolonged and predictable period of time exists today in academic and industrial research groups. One of the most feasible approaches for achieving a prolonged and predictable drug delivery in the GI tract is to control the gastric residence time (GRT), i.e. gastro retentive dosage form (GRDFs or GRDS). GRDFs extend significantly the period of time over which the drugs may be released. They not only prolong dosing intervals, but also increase patient compliance beyond the level of existing controlled release dosage form. To achieve gastric retention, the dosage form should satisfy certain requirements; primarily, the dosage form must be able to withstand the forceful peristaltic waves in the stomach and the constant contractions, grinding and churning. To function as a gastric retention device, it must resist premature gastric emptying. Once the purpose has been served, the device should be removed from the stomach with ease (Ganesh NS, Kavitha and Mani T *et al.,* 2010).

Floating drug delivery systems

These systems float on the gastric medium for a longer duration of time during which the drug diffuses solely out of the dosage form, thereby, sustaining the release of the drug (Dada khalander, yajaman sudhakar, kn jayaveera *et al.,* 2011).

Classification

The floating drug delivery systems are classified into two categories on the basis of formulation variables:

(1) Effervescent system

(2) Non effervescent system

Effervescent floating dosage form

These are matrix types of systems prepared using swellable polymer such as methylcellulose and effervescent compounds like sodium bicarbonate, tartaric acid. When effervescent compounds come in contact with the acidic gastric contents, carbon dioxide is liberated which gets entrapped in the swollen hydrocolloids. This provides buoyancy to the dosage forms.

Non-effervescent floating dosage form

One of the approaches involves mixing of the drug with a gel forming hydrocolloid, which swells in contact with gastric fluid after oral administration and maintains a relative integrity of shape and bulk density of less than the unity, within the outer gelatinous barrier. The air trapped by the swollen polymer imparts buoyancy to these dosage forms. Thus, the drug is released by controlled diffusion.

Bi-layer tablets

Bilayered tablets allows for designing and modulating the dissolution and release characteristics and they are prepared with one layer of drug for immediate release while second layer designed to release drug latter, either as second dose or in an extended release manner (Mohd Yasir, Mohd Asif, Ashwani Kumar *et al.,* 2010) . Several pharmaceutical companies are currently developing bi-layer tablets for a variety of reasons, patent extension, therapeutic marketing to name a few. To reduce capital investment, modified tablet presses are used to develop and produce such tablets (Vyas S.P, Khar R.K *et al.,* 2002).

Advantages of Bi-layer tablets

- Bi-layer tablet is suitable for preventing direct contact of two drugs and thus to maximize the efficacy of combination of two drugs.
- Bi-layer tablets can be designed in such a manner as to modified release as either of the layers can be kept as extended and the other as immediate release.
- Extension of a conventional technology.
- Used in the combination therapy
- Used to deliver the loading dose and sustained dose of the same or different drugs.
- Used for bi-layer floating tablet in which one layer is floating layer another one is release layer of the drug.

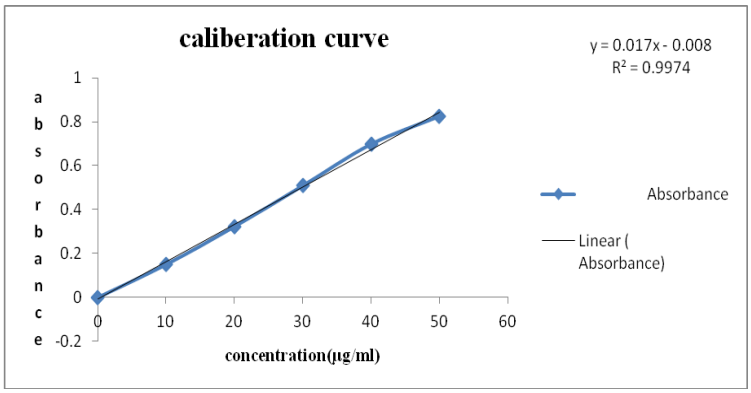

Figure 1
Construction of Calibration Curve

Functional Group	Frequency (cm^{-1})
Alcohol –OH stretching	3271.10
Alkyl C-H stretching	2925.37,2676.74
Aromatic C=C bending	1562.69
Ester	1300.49
Aromatic C-H bending	881.73

2. MATERIALS USED

Sumatriptan succinate, HPMC K 15M, HPMC K 100M, Sodium bicarbonate, Micro crystalline cellulose, Magnesium stearate, Croscarmellose sodium, Sodium starch glycolate, Crospovidone, Carboxy methyl cellulose sodium, Polyethylene oxide, Anhydrous lactose, Poly vinyl pyrrolidone K30.

Analytical Methods

Estimation of Sumatriptan Succinate

A spectrophotometric method based on the measurement of absorbance at 282 nm in 0.1N HCl was used in the present study for the estimation of sumatriptan succinate. CALIBRATION CURVE OF SUMATRIPTAN SUCCINATE IN 0.1 N HCl (pH 1.2) AT 282 nm.

FT-IR studies

The FTIR spectra of the drug (alone), polymer (alone) and the drug-polymer (mixture) were recorded by the potassium bromide pellet method. From the infrared spectra it is clearly evident that there were no drug-polymer interactions of the drug.

3. EXPERIMENTAL METHODS

Formulation and preparation of floating sustained release portion of sumatriptan succinate

All the formulations were prepared by direct compression method using different viscosity grades of HPMC polymers in combination with sodium CMC and PEO in various ratios (designated as F1 to F-8 in Table-9).

Formulation and preperation of immediate release portion of sumatriptan succinate

All the formulations were prepared by direct compression method using different ratios of diluents (MCC and Lactose) along with different superdisintegrants (Sodium starch glycolate, crospovidone,cros carmellose sodium).

Table 1

Construction of Calibration Curve

S.no	Concentration (µg/ml)	Absorbance(nm)
1	10	0.150
2	20	0.322
3	30	0.508
4	40	0.697
5	50	0.824

Table 2

Composition of Sustained Release Portion

Ingredients	%CUMMULATIVE DRUG RELEASE							
	FSR1	FSR2	FSR3	FSR4	FSR5	FSR6	FSR7	FSR8
Sumatriptan succinate (mg)	140	140	140	140	140	140	140	140
HPMC K15M(mg)	75	100	-----	----	75	100	----	----
HPMC K100M(mg)	----	----	75	100	----	----	75	100
Sodium CMC(mg)	75	50	75	50	----	----	----	----
PEO(mg)	----	----	----	----	75	50	75	50
Sodium bicarbonate (mg)	15	30	15	40	40	40	40	40
MCC(mg)	43.5	28.5	43.5	18.5	18.5	18.5	18.5	18.5
Magnesium stearate(mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5

Procedure for preparation of immediate release portion

Sumatriptan succinate and all other ingredients were individually passed through sieve ≠ 60. All the ingredients were mixed thoroughly in polythene bag for an hour. The powder mixture was lubricated with magnesium stearate. The tablets were prepared by using direct compression method.

Procedure for preparation of sustained release portion

Sumatriptan succinate and all other ingredients were individually passed through sieve ≠ 60. All the ingredients were mixed thoroughly by polythene bag for an hour. The powder mixture was lubricated with magnesium stearate. The tablets were prepared by using direct compression method.

Procedure for preparation of bilayered tablets

Initially hardness was fixed upto 5.The optimized formulations of sustained release portion (FSR4 & FSR8) blends were placed in the die cavity. It was compressed partially. Then optimized immediate release portion formulation (FIR3) was placed in the die cavity. Hardness was slightly increased and directly compressed to get a bilayered tablet.

Composition of SR layer

(Ref Table 2)

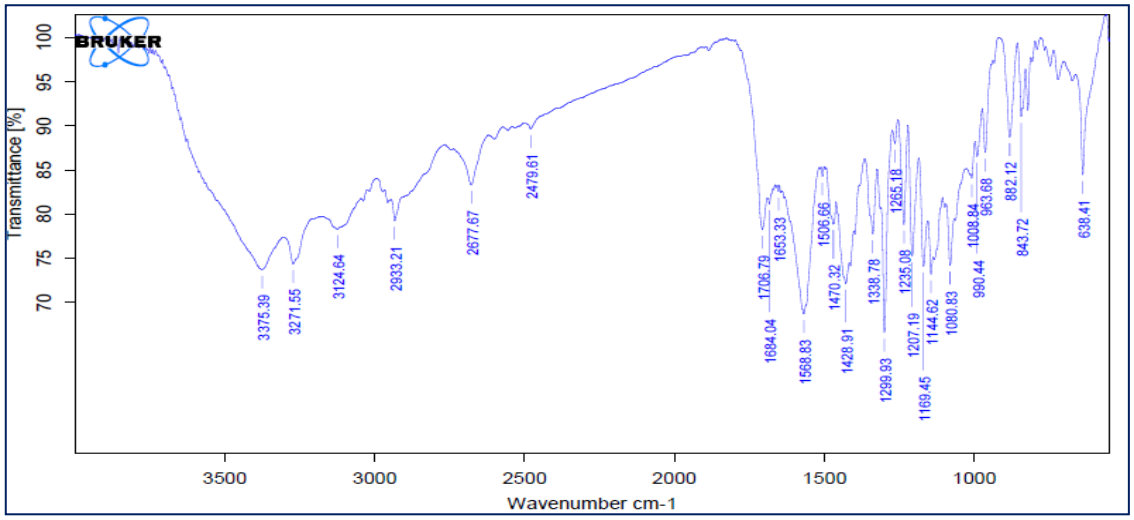

Figure 2

FT-IR OF SUMATRIPTAN-HPMC

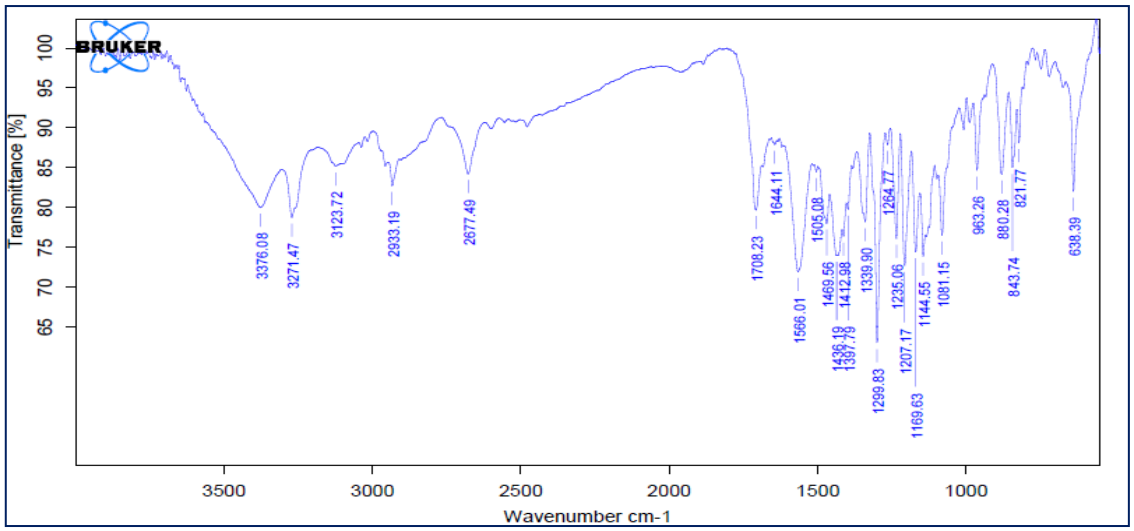

Figure 3

FT-IR OF SUMATRIPTAN-SODIUM CMC

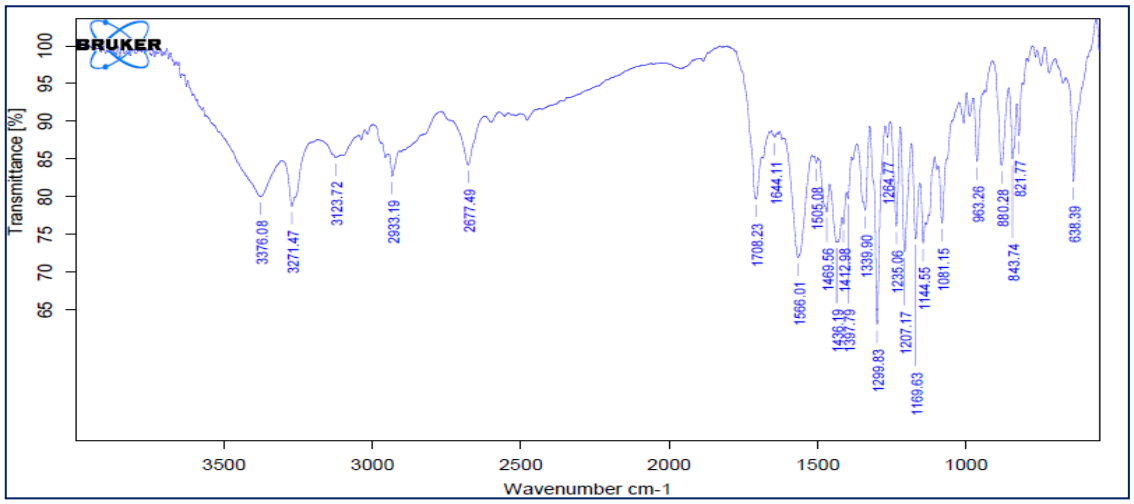

Figure 4

FT-IR OF SUMATRIPTAN-PEO

Composition of IR layer

(Ref Table 3)

Evaluation of tablets

The formulated tablets were evaluated for the following physicochemical characteristics: General appearance. The formulated tablets were assessed for its general appearance and observations were made for shape, color, texture and odor (Podczeck F, Drake K.R, Neton J.M.*et al.,* 2008).

Hardness

Hardness of the tablet was determined by using the pfizer hardness tester. The lower plunger was placed in contact with the tablet and a zero reading was taken. The plunger was then forced against a spring by turning a threaded bolt until the tablet fractured. As the spring was compressed a pointer rides along a gauge in the barrel to indicate the force.

Weight Variation

20 tablets were selected and weighed collectively and individually. From the collective weight, average weight was calculated. Each tablet

weight was then compared with average weight to ascertain whether it was within the permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.

Friability test

20 previously weighed tablets were placed in the friability apparatus, which was given 100 revolutions and the tablets were reweighed. The percentage friability was calculated by using the following formula,

Percentage friability = (initial weight-final weight /initial weight) × 100.

Drug content

20 tablets of each formulation were weighed and powdered. The quantity of powder equivalent to 100 mg of sumatriptan succinate was transferred in to a 100 ml volumetric flask and the volume adjusted to 100ml with 0.1N HCl. Further 1ml of the above solution was diluted to 100 ml with 0.1N HCl and the absorbance of the resulting solution was observed at 282 nm.

In vitro Buoyancy studies (for SR layer)

The *in vitro* buoyancy was determined by floating lag time, and total floating time. The tablets were placed in a 100ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and the duration of the time the tablet constantly floats on the dissolution medium was noted as the Total Floating Time respectively (TFT).

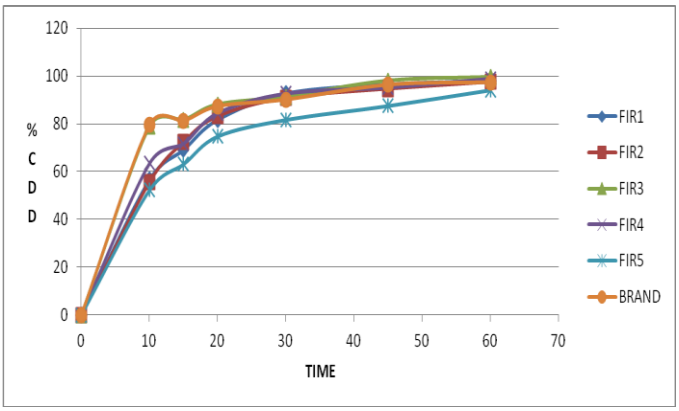

Figure 5
Dissolution profile of immediate release portion

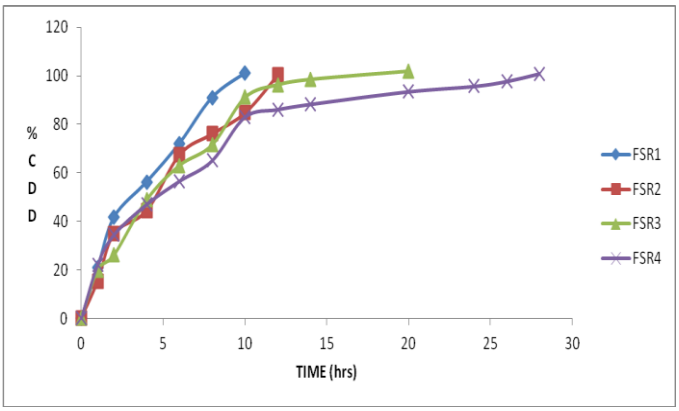

Figure 6
Dissolution profile of sodium CMC based sustained release portion

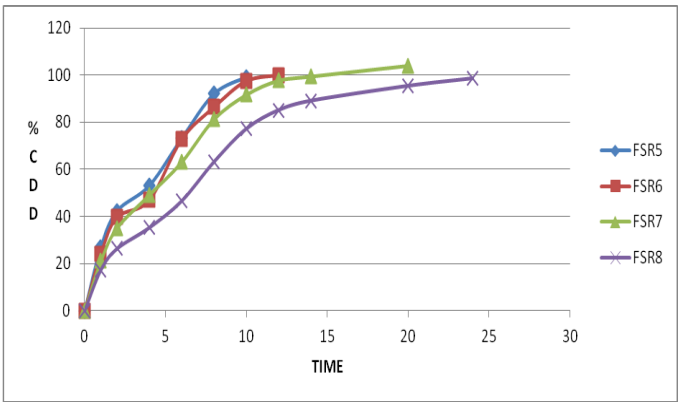

Figure 7
Dissolution profile of PEO based sustained release portion

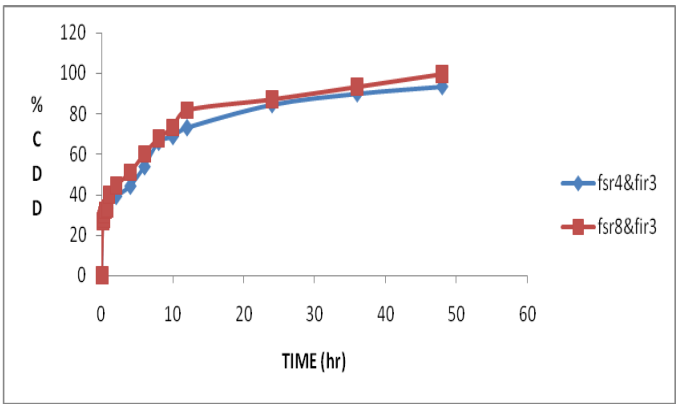

Figure 8
Dissolution profile of bilayered tablets

Dissolution Study

900ml 0f 0.1 HCl was placed in the vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37 ± 0.5 °C. Tablet was placed in the vessel and the vessel was covered, the apparatus was operated till 100%

release is attained at 50 rpm. At definite time intervals, 5 ml of the fluid was withdrawn; filtered and again 5ml of the fluid was replaced. Suitable dilutions were done with the dissolution fluid and the samples were analyzed spectrophotometrically at 282 nm.

Release Kinetics

The analysis of drug release mechanism from a pharmaceutical dosage form is an important but complicated process and is practically evident in the case of matrix systems. As a model-dependent approach, the dissolution data was fitted to four popular release models such as zero-order, first-order, diffusion and Peppa's- Korsemeyer equations, which have been described in the literature. The order of drug release from matrix systems was described by using zero order kinetics or first orders kinetics (Podczeck, Drake K.., Neton J.M.*et al.,* 2008) The mechanism of drug release from the matrix systems was studied by using Higuchi equation and Peppa's- Korsemeyer equation. The results are given in Tables.

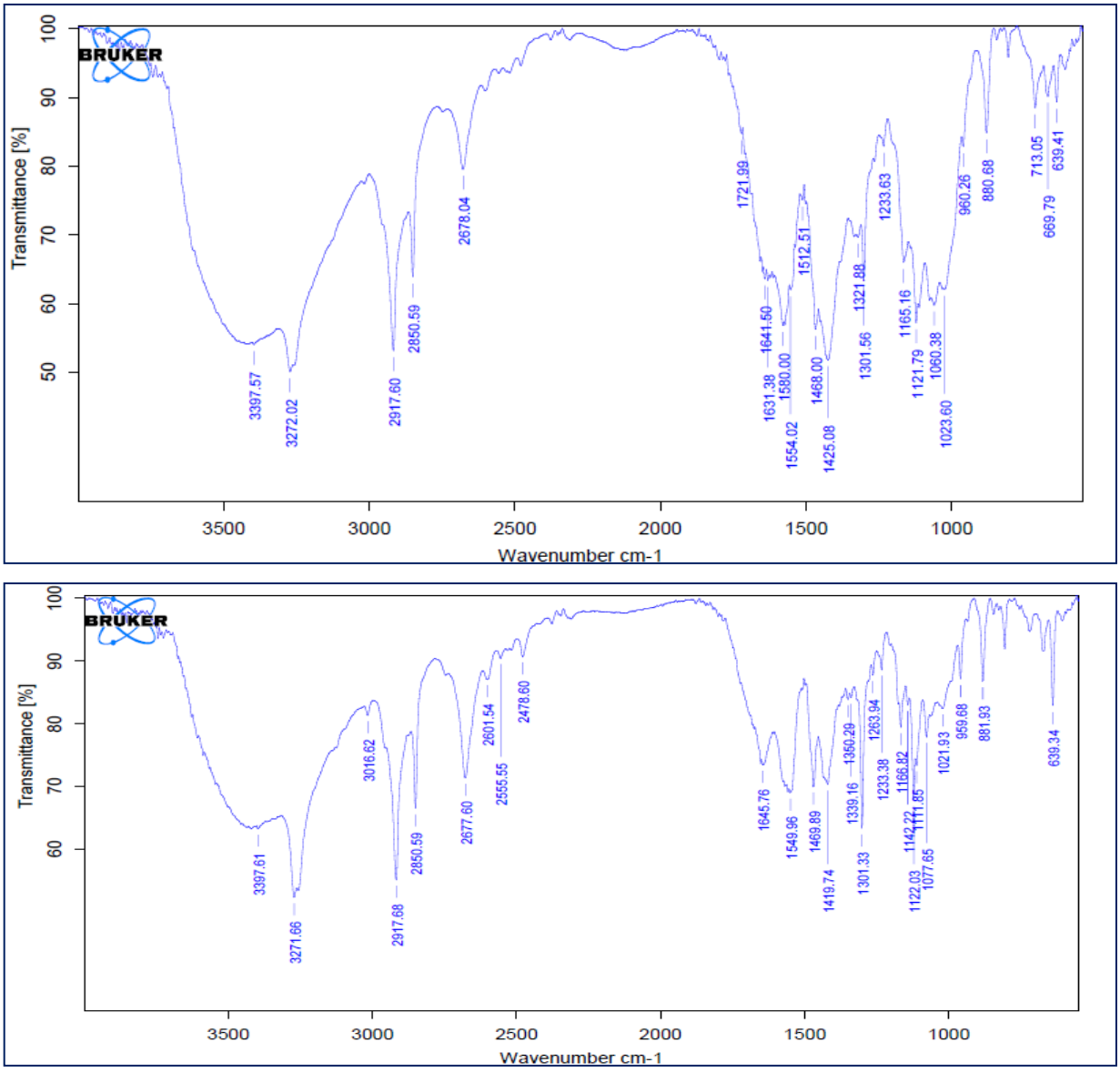

Figure 9

FT-IR OF BILAYERED OPTIMIZED FORMULATION (BL43 AND BL83)

Zero Order Release Kinetics

It defines a linear relationship between the fractions of drug released versus time.

$$Q = k_o t$$

Where, Q is the fraction of drug released at time t and k_o is the zero order release rate constant.

A plot of the fraction of drug released against time will be linear if the release obeys zero order release kinetics (Vyas S.P, Khar R.K *et*

al., 2002).

First Order Release Kinetics

Wagner assuming that the exposed surface area of a tablet decreased exponentially with time during dissolution process suggested that drug release from most of the slow release tablets could be described adequately by apparent first-order kinetics. The equation that describes first order kinetics is

$$\ln (1-Q) = - K_1 t$$

Where, Q is the fraction of drug released at time t and k_1 is the first order release rate constant.

Thus, a plot of the logarithm of the fraction of drug remained against time will be linear if the release obeys first order release kinetics (Podczeck F, Drake K.R, Neton J.M *et al.,* 2008).

Higuchi equation

It defines a linear dependence of the active fraction released per unit of surface (Q) on the square root of time.

$$Q=K_2 t^{1/2}$$

Where, K2 is the release rate constant.

A plot of the fraction of drug released against square root of time will be linear if the release obeys Higuchi equation. This equation describes drug release as a diffusion process based on the Fick's law, square root time dependant.

Power Law

In order to define a model, which would represent a better fit for the formulation, dissolution data was further analyzed by Peppa's and Korsemeyer equation (Power Law).

$$M_t/M_\alpha = K.t^n$$

Where, M_t is the amount of drug released at time t and M_α is the amount released at time α, thus the M_t/M_α is the fraction of drug released at time t, k is the kinetic constant and n is the diffusion exponent. To characterize the mechanism for both solvent penetration and drug release n can be used as abstracted in Table. A plot between log of M_t/M_α against log of time will be linear if the release obeys Peppa's and Korsemeyer equation and the slope of this plot represents "n" value (Vyas S.P, Khar R.K *et al.,* 2002).

4. RESULTS AND DISCUSSION

FT-IR studies

(Ref Figures 2-4)

Preformulation Studies

Sustained Release portion

(Ref Table 4)

Immediate release portion

(Ref Table 5)

Formulation Studies

Sustained release layer

(Ref Table 6)

Immediate release portion

(Ref Table 7)

Dissolution Profiles

Immediate Release Formulations

(Ref Table 8 & 9; Figures 5 & 6)

Optimization of Floating Lag Time

(Ref Table 10)

Peo Based Formulations

(Ref Table 11; Figure 7)

Kinetics of Sustained Release Formulations

(Ref Table 12)

Dissolution Profile of Bilayered Tablets

(Ref Table 13 & 14; Figure 8)

Evaluation of floaing lag time and thickness

(Ref Table 15)

Accelerated Stability Studies

Assay values

(Ref Table 16 & Figure 9)

5. DISCUSSION

Pre-formulation studies of drug were performed to characterize the sumatriptan succinate. The powder flow properties of sumatriptan succinate were studied to evaluate compressibility of the sumatrriptan succinate, since it has to be formulated as tablet. The results obtained are bulk density 0.39 mg/ml and tapped density was 0.458 mg/ml and Hausner's ratio 1.174. The results showed that the compressibility index of sumatriptan succinate is 14.847, which indicates that the sumatriptan succinate has good flow properties. The drug solution was prepared in p^H1.2 medium (0.1 N HCl) and scanned using UV-Spectrophotometer in the stage of 400 – 200 to determine the λ max. The λ max of sumatriptan succinate was found to be at 282 nm. So calibration curve, assay and dissolution was performed in p^H1.2 medium (0.1 N HCl). The drug – excipients compatibility studies show that there was no physical and chemical incompatibility of sumatriptan succinate with excipients studied at given conditions. Sumatriptan succinate was formulated by using direct compression. The optimized formulations of both sustained release and immediate release formulations were compressed together to get bilayered tablets.These were evaluated for thickness, swelling index, floating lag time and *in vitro* dissolution studies.Both the bilayered formulations (BL43 and BL83) gave sustained release more than 24 hrs and floating lag time with in 5 mins. So the objective is fulfilled. Accelerated stability studies of the optimized bilayered formulations were done at 40° C±2, and at 75%± 5 RH for three months. From the above data, it was observed that, there is no much variation with respect to appearance, hardness, thickness and drug content. This indicates that the formulation was stable at stored at temperature 40°C±2, relative humidity 75±5% for three months.

Table 4

Preformulation studies of sustained release portion blend

Formulation code/Parameter	Bulk density(mg/cc)	Tapped density(mg/cc)	Angle of repose(°)	Compressibility index (%)	Hausners ratio
F1	0.49	0.57	27.40	14.04	1.16
F2	0.48	0.55	26.06	12.72	1.14
F3	0.46	0.53	24.38	13.20	1.15
F4	0.43	0.49	23.72	12.24	1.14
F5	0.41	0.47	21.94	12.76	1.14
F6	0.39	0.44	20.48	11.36	1.12
F7	0.55	0.64	26.21	14.06	1.16
F8	0.53	0.61	25.74	13.11	1.15

Table 5

Preformulation studies of immediate release portion blend

Formulations	Bulk density (mg/cc)	Tapped density (mg/cc)	Angle of repose(°)	% Compressibility	Hausners ratio
F1	0.53	0.62	26.24	13.120	1.19

F2	0.45	0.55	25.42	11.18	1.17
F3	0.52	0.62	29.24	12.120	1.13
F4	0.47	0.54	27.68	12.96	1.15
F5	0.46	0.53	25.82	13.20	1.15

Table 6

Formulation studies of sustained release layer

Formulation code/Parameter	Hardness (kg/cm^2)	Weight variation	Friability (%)	Content uniformity (%)
F1	6±0.21	Pass	0.18	99.17
F2	6±0.36	Pass	0.22	99.23
F3	6±0.51	Pass	0.43	100.43
F4	6±0.48	Pass	0.20	99.72
F5	6±0.65	Pass	0.38	100.53
F6	6±0.55	Pass	0.12	99.89
F7	6±0.72	Pass	0.24	98.91
F8	6±0.39	Pass	0.16	100.13

Table 7

Formulation studies of immediate release portion

Formulation	Weight variation	Hardness (kg/cm^2)	Friability (%)	Content uniformity (%)	Disintegration Time (min)
F1	Pass	7±0.45	0.12	99.59	5'30''
F2	Pass	7±0.28	0.52	99.48	4'35"
F3	Pass	7±0.23	0.11	99.61	1'48"
F4	Pass	7±0.57	0.63	98.67	2'51"
F5	Pass	7±0.69	0.26	100.02	1'57"

Table 8

Dissolution Profile of immediate release portion

Time	%CUMMULATIVE DRUG RELEASE					
	FIR1	**FIR2**	**FIR3**	**FIR4**	**FIR5**	**BRAND**
10	56.73±1.59	55.60±1.84	78.87±1.95	63.43±1.77	52.27±1.25	79.45±1.56
15	69.17±0.92	72.32±0.44	81.65±0.68	71.67±0.32	63.08±0.62	81.22±0.63
20	81.80±0.94	83.14±1.56	88.15±0.73	84.46±0.63	74.71±1.37	87.25±1.09
30	92.78±0.56	90.81±0.61	91.39±1.87	92.63±0.27	81.62±0.49	90.05±0.18
45	96.56±1.73	94.89±0.58	98.07±1.23	95.17±0.35	87.47±1.37	96.26±1.29
60	98.16±0.96	97.46±0.89	99.56±0.67	98.82±1.38	94.04±0.16	97.25±0.61

Table 9

Dissolution profile of sodium CMC based sustained release Portion

TIME	%CUMMULATIVE DRUG RELEASE			
	FSR1	**FSR2**	**FSR3**	**FSR4**
1	21.04	15.47	20	22.08
2	41.75	35.04	26.11	34.43

4	56.24	44.48	48.95	46.99
6	72.10	67.58	63.07	56.56
8	91.05	76.12	71.57	65.05
10	101	98.82	91.13	83.06
12		100.5	96.4	86.14
14			98.64	88.32
20			102.01	93.51
24				95.72

Table 10

Floating lag time of sodium CMC based sustained release portion

Formulation	Floating lag time
FSR1	<30mins
FSR2	10-12mins
FSR3	20-25mins
FSR4	45sec-2mins

Table 11

Dissolution profile of PEO based sustained release portion

TIME	%CUMMULATIVE DRUG RELEASE			
	FSR5	**FSR6**	**FSR7**	**FSR8**
1	26.95	24.15	21.04	17.26
2	42.39	39.69	35.08	26.34
4	53.14	47.02	49.19	35,23
6	73.18	72.78	63.08	46.55
8	92.09	86.50	81.28	63.16
10	99.16	97.60	91.74	77.19
12		100.01	97.81	85.12
14			99.54	89.1
20			104.1	95.39
24				98.57

Table 12

Release kinetics for sustained release portions

Formulation	Zero order(K_0)	First order(K_1)	Higuchi(r^2)	Koersmeyers-peppas	
				N	r^2
FSR1	0.836	0.917	0.981	0.664	0.977
FSR2	0.926	0.986	0.076	0.748	0.972
FSR3	0.819	0.893	0.981	0.650	0.987
FSR4	0.045	0.974	0.948	0.449	0.963
FSR5	0.773	0.812	0.986	0.562	0.985
FSR6	0.832	0.850	0.981	0.584	0.977
FSR7	0.764	0.864	0.988	0.602	0.992
FSR8	0.580	0.973	0.963	0.591	0.974

Table 13

Dissolution profile of bilayered tablets

TIME	%CUMMULATIVE DRUG RELEASE	
	BL83	BL43
10	26.7±0.74	28.02±1.61
15	27.93±0.53	29.21±0.23
20	30.03±0.98	33.02±0.57
30	32.29±0.73	33.23±0.25
45	32.92±0.52	33.42±1.23
1	39.76±0.84	36.98±0.79
2	44.40±0.52	39.10±1.83
4	50.89±0.58	44.13±0.27
6	60.06±0.63	53.72±1.33
8	67.89±0.85	65.8±0.89
10	73.27±0.74	68.67±0.94
12	81.77±0.90	72.96±0.95
24	87.15±0.56	84.33±0.58
36	93.37±1.63	89.76±0.35
48	99.70±1.56	93.26±0.47

Table 14

Evaluation of swelling index of the bilayered tablets swelling indices of bilayered tablets

Time	SWELLING INDEX	
	BL43	BL83
0	0	0
1	90.05	78.76
2	135.36	110.37
3	170.8	145.89
4	210.87	182.57
5	256.43	237.13
6	297.63	278.78
7	335.12	306.46
8	361.08	349.81
9	386.32	367.85
10	391.67	376.74
11	394.37	384.77
12	397.07	389.56

Table 15

Floating lag time and thickness of bilayered tablets

Formulation	Thickness	Floating lag time
BL43	6 mm	45 sec – 80 sec
BL83	6 mm	180 sec – 300 sec

Table 16

Accelerated stability studies of bilayered tablets

FORMULATION	DRUG CONTENT (%)			
	INITIAL	FIRST MONTH	SECOND MONTH	THIRD MONTH
BL43	99.17	98.66	98.17	97.86
BL83	100.61	99.76	98.83	98.19

6. CONCLUSION

In the present work, an attempt was made to develop and optimize sustained release floating bilayered tablets of Sumatriptan succinate. Migraine is a form of headache where the patient suffers from throbbing headache. In about 49% of patients headache reoccurs. So another dose (100 mg) of Sumatriptan has to be given. If the headache is not subsiding, then has to be given. To avoid these many administrations, an attempt has been made to decrease the dosing frequency. Sustained release portion along with immediate release portion (loading dose) is combined to produce the bilayered tablet. Similarity factor, F2 for optimized immediate release portion was found to be 90.17. The optimized sustained release portion and immediate release portion (FSR4 & FIR3, FSR8 & FIR3) were compressed together to get bilayered tablet. Optimized floating bilayered tablets (BL43 and BL83) released 84.33% & 87.15 % drug in 24 hrs respectively in 0.1 N HCl. The release of the sustained layer follows first order, non-fickian diffusion. The optimized bilayered tablets were studied for *in-vitro* drug release and accelerated stability studies. The optimized tablets formulations were found to be stable during the short term accelerated stability studies (3 months). FT-IR studies indicated that there were no drug-excipient interactions. Hence, it can be concluded that sustained release floating bilayered tablets of Sumatriptan succinate have been successfully formulated and scale-up studies can be conducted after *in vivo* studies.

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